



UNITED STATES PATENT AND TRADEMARK OFFICE

HL

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/021,425	10/30/2001	Bolten L. Suzanne	3196/00 US	2066
26648	7590	02/10/2004	EXAMINER	
PHARMACIA CORPORATION GLOBAL PATENT DEPARTMENT POST OFFICE BOX 1027 ST. LOUIS, MO 63006			PATTERSON, CHARLES L JR	
			ART UNIT	PAPER NUMBER
			1652	
DATE MAILED: 02/10/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/021,425	SUZANNE ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Charles L. Patterson, Jr.	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### **Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on \_\_\_\_.

2a)  This action is **FINAL**.                    2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## **Disposition of Claims**

4)  Claim(s) 1-77 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) \_\_\_\_\_ is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claim(s) 1-77 are subject to restriction and/or election requirement.

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1)  Notice of References Cited (PTO-892)  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3)  Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.  
4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.  
5)  Notice of Informal Patent Application (PTO-152)  
6)  Other: \_\_\_\_\_.

Art Unit: 1652

Restriction to one of the following inventions is required under 35

U.S.C. 121:

- I. Claims 1-2, 10-29, 35, 46-49, 57-58, drawn to a nucleic acid of SEQ ID NO:1, a method of expressing a protein by using the nucleic acid, an expression cassette comprising the nucleic acid, a host cell comprising the cassette, classified in class 435, subclass 189, 320.1, 252.3, class 536, subclass 23.2.
- II. Claims 3-5, 30-34, 71-73, drawn to a hydroxylase of SEQ ID NO:2, a fusion protein comprising the enzyme, classified in class 435, subclass 189.
- III. Claims 6-7, 36-37, 59-60, drawn to a nucleic acid of SEQ ID NO:5, an expression cassette comprising the nucleic acid, classified in class 435, subclass 320.1, class 536, subclass 23.2.
- IV. Claims 8-9, 71, 74-75, drawn to an oxidoreductase of SEQ ID NO:6, a fusion protein comprising the enzyme, classified in class 435, subclass 189.
- V. Claims 38-45, drawn to an expression cassette comprising DNA encoding an enzyme from the metabolic pathway for sitosterol synthesis, a host cell comprising the cassette, a method of making one or more enzymes by using the host cell, a method of oxidizing a compound by using the host cells, classified in class 435, subclass 320.1, 252.3.
- VI. Claims 50-52, 56, drawn to an antibody to a portion of SEQ ID NO:2 and a composition comprising the antibody and a carrier, classified in class 530, subclass 287.9.

Art Unit: 1652

VII. Claims 53-56, drawn to an antibody to a portion of SEQ ID NO:6 and a composition comprising the antibody and a carrier, classified in class 530, subclass 287.9.

VIII. Claim 61, drawn to a use of a host cell with the gene of claim 1 for the manufacture of a medicament for specific purposes, classified in class 435, subclass 252.3.

IX. Claim 62-70, drawn to a composition and its use to produce spores, classified in class 536, subclass 1.11.

X. Claims 76-77, drawn to an 11 alpha hydroxylated steroid and a method of making it, classified in class 435, subclass 68.1 and class 540, subclass 2.

The inventions are distinct, each from the other because:

Groups 1-VII and IX-X are drawn to different chemical compounds that are patentably distinct.

Inventions I and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process such as make the enzyme not involved with a treatment process.

Note that claim 37 is drawn to a nucleic acid of SEQ ID NO:6. SEQ ID NO:6 is a protein so the claim apparently was meant to be directed to SEQ ID NO:5.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different

Art Unit: 1652

classification and recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles L. Patterson, Jr., PhD, whose telephone number is 571-272-0936. The examiner can normally be reached on Monday - Friday from 7:30 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-308-4242.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Charles L. Patterson, Jr.  
Primary Examiner  
Art Unit 1652

Patterson  
February 6, 2004